

### **REMARKS/ARGUMENTS**

Claims 1 and 10 are canceled in favor of new claims 21 and 22, respectively. Claims 2, 5 - 9, 12, 14 - 17, 19 and 20 are amended. Upon entry of the amendment, independent claim 21 with claims 2 - 9 and 11 - 20 dependent therefrom and independent claim 22 are presented for consideration by the Examiner.

#### Claim Rejections - 35 U.S.C. §112

The Examiner objects to the specification and rejects claims 1 - 20 under 35 U.S.C. §112 as failing to provide an enabling disclosure of how the cement is released from the inner housing prior to mixing and where the liquid component of the cement is located prior to mixing. Applicant directs the Examiner's attention to page 1 of the specification which describes in detail the background of the invention. Page 1 of Applicant's specification, lines 15 - 22 describe a two-component orthopedic cement where the liquid component is "generally provided in an ampoule which is broken and added to the powder". The two components are then thoroughly mixed to provide a malleable cement which can be manipulated and applied to the appropriate bone parts, during surgery.

The Applicant's invention relates most particularly to an apparatus for storage of the powder component of the orthopedic cement in a manner which leaves the powder component in a mixing chamber upon separation of an inner housing from an outer housing which defines the mixing chamber. Applicant's specification, page 5, line 33, - page 6, line 3, and page 7, lines 27 - 32, describe separation of the inner housing from the outer housing, which leaves the "cement powder 4" (powder component) in the mixing chamber defined by the outer housing. The inner housing is then discarded and the "standard mixing procedure for this type of mixing arrangement is carried out." (specification, page 7, lines 30-32) The liquid component of the orthopedic cement is added to the powder component in the mixing chamber and mixing is carried out as is well known by those of skill in the art.



The specification clearly includes an enabling description of how the powder and liquid components of an orthopedic cement are placed in the mixing chamber where mixing is carried out according to procedures which are well known in the art.

Applicant respectfully requests withdrawal of the Examiner's 35 U.S.C. §112 rejection of claims 1 – 20 and objections to the specification.

Claim Rejections - 35 U.S.C. §103

Claim 1 is canceled in favor of new claim 21, which recites in pertinent part as follows:

an inner housing defining a powder component storage chamber containing the powder component, **said powder component storage chamber having an open end surrounded by a sealing edge**, said inner housing secured to said outer housing **with said sealing edge in sealing contact with said inside surface to close the open end of said powder component storage chamber**, said inner housing being removable from said outer housing to open said powder component storage chamber and release said powder component into said mixing chamber. (emphasis added)

Claim 21 recites structures and relationships that are not disclosed, taught or suggested in the art cited by the Examiner. U.S. Patent No. 6,148,996 to Morini (hereinafter Morini) and U.S. Patent No. 3,156,369 to Bowes et al (hereinafter Bowes) disclose containers having inner housings where the bottom portion of the inner housing is ruptured by a cutting element to release a component stored in the inner housing. Morini and Bowes do not disclose, teach or suggest an open-ended powder component storage chamber that is sealed by engagement of a sealing edge of the powder component storage chamber with the inside surface of a mixing chamber defined by an outer housing component as recited in claim 21.

U.S. Patent No. 5,114,240 to Kindt-Larsen et al (hereinafter Kindt-Larsen) discloses a method and device for preparing a mixture of a solid and a liquid component where the solid and liquid components are stored in a mixing chamber. The solid and liquid components are separated by a breakable membrane 14 across an opening in the



end wall of the chamber. The "feather edge" (components 28, 29a) pointed out by the Examiner provides a seal to prevent liquid component from entering the space between the first and second cylinders 10, 18 (see Kindt-Larsen, column 8, lines 18 – 55 and Figures 8, 9). The seal formed by sealing fins 28 and O-ring 29a allow pressure to accumulate sufficient to break the membrane 14 while preventing liquid component from passing between the first and second cylinders 10, 18. The arrangement of Kindt-Larsen does not disclose, teach or suggest the limitations of claim 21.

The Examiner's proposed combination does not comply with MPEP §§ 2142 and 2143

MPEP §§ 2142 and 2143 clearly require that there be some motivation, either in the references themselves, or in the knowledge of one of skill in the art to combine the reference teachings. The Examiner's stated motivation (Office Action, page 4, lines 4-6) does not make sense technically and finds no basis in the references. There is no motivation for one of skill in the art to combine the teachings of either Morini or Bowes with those of Kindt-Larsen. The structures of Morini and Bowes are incompatible with the Examiner's proposed modification. Even if combined, the teachings of the cited references fail to disclose, teach or suggest the recitations of claim 21.

Claim 21 is patentable for at least these reasons.

Claims 2 - 9 and 11 - 20 depend directly or indirectly from claim 21 and are patentable for at least the reasons stated in support of claim 21.

Claim 22 is presented instead of canceled claim 10. Claim 22 recites in pertinent part as follows:

disposing said powder component in a powder component storage chamber defined by an inner housing, said chamber having an open end surrounded by a sealing edge;

securing said inner housing to an outer housing defining a mixing chamber with an inside surface, said sealing edge in sealing contact with said inside surface to close said open end of said powder component storage chamber; and

removing said inner housing from said outer housing, thereby separating said sealing edge from said inside surface to release said powder component into said mixing chamber.



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For the reasons stated in support of claim 21 above, the art cited by the Examiner, either alone or in combination, does not disclose, teach or suggest the limitations recited in claim 22. Claim 22 is patentable over the art cited by the Examiner for at least these reasons.

**For all the foregoing reasons,** Applicant respectfully requests allowance of claims 21, with claims 2 - 9 and 11 - 20 dependent therefrom, and claim 22.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read 'Thomas J. Menard', written over a horizontal line.

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